



Seton Hall University School of Law
Health Law Forum

Health Law Outlook



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Are “Smart Choices” a “Bad Decision”?

Self-Regulation in the Food Industry

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Lucky Charms, Froot Loops, Ritz Bits Peanut Butter Chocolatey Blast Crackers—historically, children had to persuade hesitant parents to put these items in the grocery cart.¹ Today, these and many other sugary, highly processed foods are granted the coveted “Smart Choices” check mark, indicating to consumers that they have made a nutritious food choice.² But whose standards indicate whether or not food options are “smart”?

“Smart Choices” products are self-regulated by the Smart Choices Program (SCP). Many individuals and entities alike, however, question the merit of the SCP and worry that misrepresentation and misconceptions arise from labeling

certain products Smart Choices. They ask whether alternative regulatory measures by the government may, in fact, be more appropriate.

The Origins and Details of Smart Choices Self-Regulation

In 2006, the Federal Trade Commission and the Department of Health and Human Services recommended that food companies “explore labeling initiatives, including icons and seals, to identify lower-calorie, nutritious foods clearly and in a manner that does not mislead consumers.”³ In response, many companies began self-regulating their products, but their standards and symbols were not uniform. In 2007, the Keystone Center, a nonprofit health group, recognized this national issue of labeling confusion and assembled a Food and Nutrition Roundtable to “explore science-based nutrition labeling solutions to help improve the American diet and enhance public health.”⁴ This

Roundtable consisted of a coalition of different organizations and individuals, including scientists, academics, health and research organizations, food manufacturers, and retailers.⁵ At this Roundtable, the idea of making the “Nutrition Facts panel more relevant and meaningful to consumers emerged as a topic of focus.”⁶ Discussing this concept “led to a discussion of front-of-pack (FOP) nutrition labeling and the need for a uniform FOP nutrition labeling program to help bring consistency and clarity to the marketplace.”⁷

As a result of this discussion, the Roundtable developed the Smart Choices name and logo.⁸ If a food group is approved, it receives two SCP labels: one is “a green checkmark symbol indicating that a food bearing the checkmark has met certain nutrient criteria; the other states the number of calories per serving and the number of servings in the package.”⁹ The SCP website states that “the uniform and

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Reverse Payments

A Lawful Settlement Strategy or Unlawful Reduction in Competition?

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Reverse Payments Reduce the Drug Price Competition Intended by the Hatch-Waxman Amendments

Congress enacted the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act) in 1984 to help reduce the cost of pharmaceutical drugs by encouraging the entry of generic drugs into the market.¹ Under the Hatch-Waxman Act, a generic drug company may file an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration (FDA), which requires submission of significantly less safety and efficacy data than is required by a brand drug in order to get market



approval.² Generally the generic company must also file a paragraph IV certification along with the ANDA, stating that it will not infringe upon the brand company's patent or that the brand company's patent is invalid.³ FDA will grant a 180-day ex-

clusivity period to the first generic company to file a paragraph IV certification, blocking any other generic companies from marketing the same drug during this time.⁴ Once a paragraph IV certification is filed, the brand company has forty-five days to file suit against the generic for patent infringement.⁵ As a benefit to the brand company, FDA will refuse to grant the generic company market approval of the generic drug for thirty months starting from the initiation of this litigation.⁶

In the early 2000s brand and generic companies began to use so-called “reverse payments” as part of paragraph IV litigation settlements. Reverse payments occur when the brand company pays the generic company, either in money or some form of other consideration, to delay launch of the generic drug until shortly before the patent expires.⁷ Because the brand drug remains the only available option for con-

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Managing Pharmacy Benefit Managers

The Effect of Transparency Reform on “Big Business” and “Small Patient”

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The current legislative focus on healthcare reform has seemingly pitted the “small patient,” who is facing ever-increasing healthcare costs and perhaps a lack of healthcare coverage altogether,¹ against “big business,” a healthcare industry whose profits are apparently at the expense of patients who depend on it for their very wellbeing.² In the midst of this adversarial reform climate, one proposal stands to benefit both sides: the addition to current measures increasing healthcare access of transparency requirements for pharmacy benefit managers (PBM).

Introduction to Pharmacy Benefit Managers (PBMs)

Pharmacy benefit managers act as a species of “middleman” in the drug supply chain linking pharmaceutical manufacturers to patients. Specifically, PBMs link pharmaceutical manufacturers, pharmacies, and benefit providers.³ They contract with manufacturers on behalf of benefit providers to obtain brand name and generic drug coverage.⁴ In addition, they contract with retail or mail-order pharmacies to provide access to these drugs for benefit provider plan enrollees.⁵ PBMs managed drug benefits for fifty-seven percent of the U.S. population in 2004.⁶

In negotiating these relationships, PBMs do more than act as an intermediary; they perform several other functions that have subjected their role to scrutiny:

☼ Development of formularies, including generic and therapeutic substitution. PBMs primarily use formularies, or lists of PBM-approved drugs, to manage benefits for benefit providers.⁷ In effect, PBMs will rank available prescription drugs by desirability, with some ex-

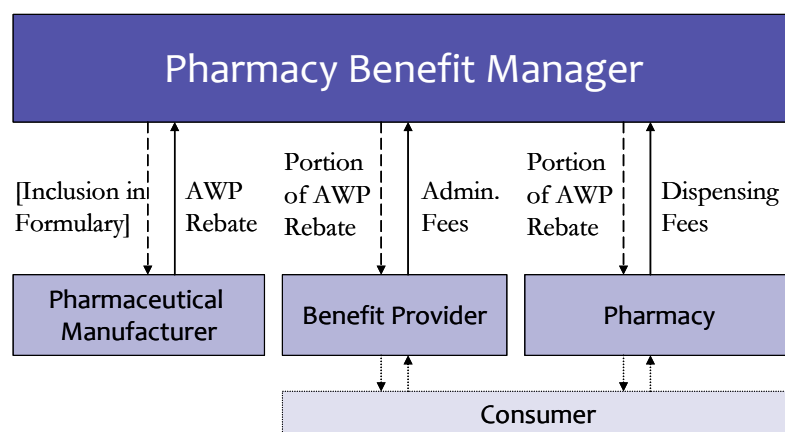
cluded altogether from the formulary, and will price patient co-pays accordingly.⁸ Generally, PBMs utilize a three- or four-tiered co-pay arrangement, with associated co-pays increasing in each tier: (1) generic drugs; (2) brand-name drugs with no generic equivalents; (3) brand-name drugs with generic equivalents; and (4) optionally, as negotiated by the benefit provider plan, drugs excluded from the formulary, such as lifestyle drugs.⁹ In addition to saying “yes” or “no” to a particular pharmaceutical treatment option and setting the patient price accordingly, PBMs also exercise considerable power over how a pharmacy fills a particular individual prescription.¹⁰ PBMs can direct pharmacies to substitute generic versions of drugs for brand-name prescriptions, without needing physician approval, or to substitute therapeutically distinct but equivalent (and likely less expensive) drugs, subject to physician authorization.¹¹ By providing significant “pocketbook” incentives for patients filling pharmacy prescriptions to switch to less expensive alternatives, PBMs manage the costs of the benefit providers’ prescription benefits.

☼ Negotiation of rebates and downstream payments. PBMs also negotiate payment streams with pharmaceutical manufacturers, retail pharmacies, and benefit providers. First, PBMs negotiate with pharmaceutical manufacturers for “rebates” of portions of the Average Wholesale Price (AWP)—the “sticker

price”—for drugs included on a PBM’s formulary. The PBM will negotiate an AWP rebate based on “(a) a percentage of AWP or some other wholesale benchmark, (b) achieving certain specified sales or market share targets, (c) preferred placement of certain drug products on the PBM[s] formulary,” or a combination of these.¹² The PBM will also incorporate AWP rebates into its agreements with pharmacies and the benefit providers. For example, the PBM will reimburse the pharmacy at a price that reduces AWP by some rebate, offset by a dispensing fee, e.g., “AWP *minus* % rebate *plus* \$ dispensing fee.”¹³ The size of this rebate will depend in part on the exclusivity of the relationship (i.e., the size of the resulting retail pharmacy network) and the number of benefit providers associated with the PBM.¹⁴ With respect to the benefit providers, the PBM will pass along some of these rebates but incorporate an additional administration charge to cover other services the PBM provides, e.g., “AWP *minus* % rebate *plus* \$ administration fee.”¹⁵ Each of these fee structures are negotiated separately with each entity, and rebates are not currently disclosed.¹⁶

☼ Other functions: Mail-order services, claims adjudication, and quality-focused programs. In addition to these primary functions, PBMs also provide ancillary services to benefit providers and patients. Most PBMs offer mail-order

(Managing PBMs, Continued on page 12)



The rebate and payment negotiation relationships among PBMs, pharmaceutical manufacturers, benefit providers, pharmacies, and consumers.

Pregnant with Power

Court Takes Control in the OTC Switch of Plan B

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The Food and Drug Administration (FDA) has struggled with the question of whether to allow the over-the-counter sale of the Plan B emergency contraceptive to young women.¹ On March 23, 2009, after six years of debate, the United States District Court for the Eastern District of New York finally ordered FDA to make Plan B available to women age seventeen and older without a prescription.² In a fifty-two page opinion, Judge Edward R. Korman scolded FDA for allowing the White House's political agenda to trump the scientific evidence that clearly showed over-the-counter Plan B to be safe for women age seventeen and over.³ Following Judge Korman's decision, a number of religious groups sought leave to challenge the outcome,⁴ but these groups were ultimately found to lack standing to intervene.⁵ The disagreement over Plan B sparks a fundamental question: is the court's intervention in ordering drug regulations appropriate when scientific findings and political agendas collide?

"[I]S THE COURT'S INTERVENTION IN ORDERING DRUG REGULATIONS APPROPRIATE WHEN SCIENTIFIC FINDINGS AND POLITICAL AGENDAS COLLIDE?"

Plan B, commonly known as the "morning-after pill," is a type of contraception that is taken after sexual intercourse to prevent unwanted pregnancy.⁶ Initially, the drug was available only by prescription.⁷ In August 2006, however, FDA approved the switch to non-prescription use of Plan B for women eighteen and over, which allowed women to obtain Plan B upon consultation with a pharmacist, also known as "behind the counter" (BTC).⁸ Judge Korman's ruling

did not alter the BTC requirements, but simply lowered the minimum age for obtaining the drug from eighteen to seventeen.⁹

The Role of FDA Generally

The public relies on FDA to make informed decisions about drug regulations. The basis for these decisions is codified in 21 U.S.C. § 393(b) of the Food, Drug, and Cosmetic Act (FDCA)—to protect and promote the public health.¹⁰ But, despite their efforts to remain a neutral body, FDA faced pressure from the White House and from certain religious groups to deny making Plan B available without a prescription.¹¹ Thus, given the highly sensitive nature of emergency contraception, FDA veered sharply away from its normal procedure.¹²

Before the implementation of the BTC regime, drugs were either available by prescription or over the counter (OTC).¹³ FDA has distinct protocol in place for all prescription-to-OTC switches to ensure that the scientific evidence is evaluated objectively.¹⁴ According to the FDCA, a drug can be sold without a prescription when the Secretary of Health and Human Services finds that a prescription requirement is not necessary for the protection of public health.¹⁵ The switch can occur either by a regulation promulgated by FDA at the request of FDA commissioner or of an interested citizen, or alternatively, a drug sponsor can request a switch, whereby rulemaking is unnecessary.¹⁶ The Commissioner may also delegate the switch operations to FDA's Center for Drug Evaluation and Research (CDER).¹⁷ The Director of the CDER will seek the help of agencies within its control and advice from outside experts and has the ultimate decision of whether to approve a switch.¹⁸

The Role of FDA—and the Court—in the Plan B Switch

As Judge Korman outlines in his opinion, politics and protocol collided in the Plan B switch recommendations.¹⁹

On February 14, 2001, a Citizen Petition was submitted to FDA asking for a complete OTC switch of Plan B without age restrictions.²⁰ Although FDA recognized that there was sufficient data to approve



the switch, then-FDA Deputy Commissioner Dr. Lester Crawford and Commissioner Dr. Mark McClellan later testified that at the time, discussions regarding the "political sensitivity" of the possible switch of Plan B pervaded the decision process.²¹ Judge Korman notes that testimony of FDA officials reveals that politics and ideology played a "determinative role" in choosing members for the advisory committee that would ultimately decide whether to approve the Plan B switch.²² The Advisory Committee nonetheless approved the Plan B switch.²³ The FDA, however, did not follow its advice.²⁴ Judge Korman points out that "the FDA has followed advisory committee recommendations in every OTC switch application in the last decade."²⁵ Judge Korman further references similar occurrences within FDA over the subsequent five years, which indicated that the agency continued to deviate from its routine protocol.²⁶ Even when the drug was made available for OTC use to women eighteen and over, it was still placed behind the pharmacy counter, so that women who purchased the drug were monitored.²⁷

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To Tell or Not to Tell—That Is the Question

Physician Disclosure of Medical Errors

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Imagine this scenario: a patient visits the hospital and undergoes a cardiac procedure. He is discharged a few days later. He continues to have some difficulties, and his cardiologist does an outpatient echo-cardiogram, which reveals a collection of blood adjacent to the heart. The patient is brought back to the operating room, where a small incision is made below the xiphoid process and a catheter advanced in an attempt to “suction” out this blood. Massive bleeding is encountered and the patient expires on the operating room table.

What should the physician tell the patient’s wife and daughter who are in the waiting room?

New Jersey’s Patient Safety Act

The Patient Safety Act (PSA),¹ a landmark piece of legislation passed in 2004, changed the paradigm for dealing with medical errors and serious adverse events in New Jersey. Previously limited to an ethical responsibility, the legislation created a legal duty to disclose medical errors to patients or their surviving families in the event of death.²

The PSA falls within the rubric of the so-called “apology laws,” which prevent the use of expressions of regret, condolences, and sympathy from use as evidence of admission of guilt in subsequent litigation.³ At least four other states have mandated disclosure of medi-

cal errors to patients.⁴ Of the fifty states and the District of Columbia, thirty-six have enacted “apology laws” protecting voluntary disclosures of medical errors.⁵

“OF THE FIFTY STATES AND THE DISTRICT OF COLUMBIA, THIRTY-SIX HAVE ENACTED ‘APOLOGY LAWS’ PROTECTING VOLUNTARY DISCLOSURES OF MEDICAL ERRORS.”

The PSA defines an “adverse event” as an event that is “a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.”⁷ A “serious, preventable adverse event” is defined in the PSA as “an adverse event that is a preventable event and results in death or loss of a body part, or disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.”⁸

The legislature stated that its intent in mandating disclosure of serious, preventable adverse events was to “increase the amount of information on systems failures, analyze the sources of these failures and disseminate information on effective practices for reducing systems failures and improving the safety of patients.”⁹ Thus, the patient must be informed of any serious preventable adverse events before the end of the episode of care, or in a timely manner if the error is discovered after the episode of care has ended.¹⁰ In addition, the Department of Health and Senior Services (DHSS) must be notified of the occurrence of the error.¹¹

In August 2006 the legislature clarified some of the ambiguous provisions of the PSA and the penalties resulting from non-compliance.¹² Physicians or medical providers are required to notify a patient of a medical error within twenty-four hours of its discovery.¹³ The patient must be notified by telephone or certified mail or in person if he is still at the facility.¹⁴ The disclosure must be documented in the patient’s chart along with details of date, time, the persons informed, and the names of all individuals present at the time the disclosure was made.¹⁵ A report to DHSS must be made within five days of the occurrence or discovery of the adverse event.¹⁶ Specific details that must be included in the report to DHSS include (a) the date and time the event occurred, (b) a brief description of the event, (c) a statement about the impact of the event on the health of the patient, (d) the date and time the facility became aware of the event, (e) how the event was discovered, (f) the immediate corrective actions the facility took to eliminate or reduce the adverse impact of the event on the patient, and (g) what steps were taken to prevent the occurrence of future similar events.¹⁷

The Act penalizes non-compliance by healthcare facilities at a rate of \$1000 per day.¹⁸ Medical providers are fined \$1000 for disclosing to neither the patient nor DHSS.¹⁹ But if there is no disclosure to the patient, while a disclosure *was* made to the Department, the fine increases to \$5000.²⁰

An Ethical Responsibility

The American Medical Association Code of Ethics describe the doctor-patient relationship as one that is “based on trust and gives rise to physicians’ ethical obligations to place patients’ welfare above their own self-interest and above obligations to other groups and to advocate for their patients’ welfare.”²¹ The clinical encounter between a patient and a doctor is described as “fundamentally a moral activity that arises from the impera-

(“To Tell or Not to Tell,” Continued on page 7)

Type of Disclosure Legally Protected	Explanation ⁶
Sympathy only	Protects physician expressions of sympathy, regret, and condolence
Admission of fault	Protects physician admissions of fault and error, as well as expressions of sympathy, regret, and condolence

'To Tell or Not to Tell,' Continued

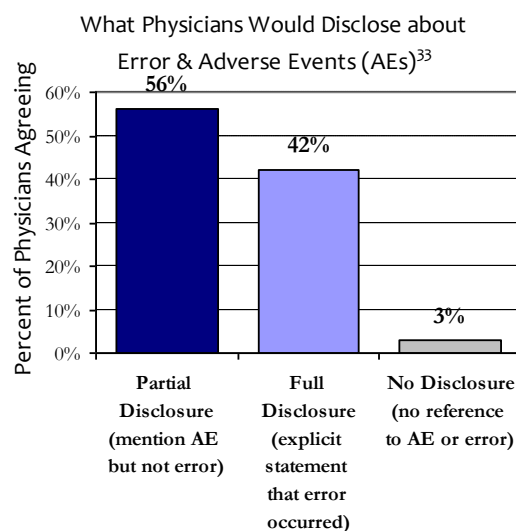
tive to care for patients and to alleviate suffering.”²² Based on the principles that trust and patient-welfare are central to the physician-patient relationship, the American Medical Association Code of Ethics states that physicians have an ethical obligation to advise patients of the occurrence of a significant medical error when “a patient suffers significant medical complications that may have resulted from the physician’s mistake or judgment.”²³ The American College of Surgeons endorses in its Code of Professional Conduct that surgeons “fully disclose adverse events and medical errors.”²⁴ The American College of Physicians’ Ethics Manual also directs physicians to disclose errors if disclosure of this information is “material to the patient’s well-being.”²⁵

Similarly, many organizations that oversee healthcare entities support disclosure of errors and adverse events. In 2001, the Joint Commission issued the first nationwide disclosure standard, which required that patients be informed about all outcomes of care, including

“unanticipated outcomes.”²⁶ The standard did not specify the content of disclosure, nor did it mandate that patients be told when unanticipated outcomes were due to error.²⁷ In 2006, the National Quality Forum endorsed full disclosure of “serious unanticipated outcomes” as one of its thirty “safe practices” for healthcare.²⁸ In legally mandating these standards in the form of the PSA, the New Jersey legislature stated that “[h]ealth care facilities and professionals must be held accountable for serious preventable adverse events.”²⁹ The necessity of a law to supplement an ethical obligation implies that the ethical imperative alone has been inadequate in creating this accountability.

The Gap Between Ideals and Reality

Most patients harmed by medical errors are never told that these errors have occurred. Interviews and surveys regarding error disclosure have shown that patients want to be informed of errors in



their medical care, to receive an explanation of the occurrence of the errors, and to learn how recurrences will be prevented.³¹ Physicians agreed with disclosure, but indicated that they “choose their words carefully” when telling patients about errors.³²

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'Smart Choices,' Continued

recognizable nutrition symbol and calorie information that can be identified at-a-glance on the front of packages can help guide consumers’ food choices at the point of purchase and in their homes.”¹⁰

The standards used in evaluating SCP food items were to be derived from “a comprehensive set of qualifying nutrition criteria derived from . . . the Dietary Guidelines for Americans, FDA standards, reports from the Institute of Medicine and other sources of authoritative dietary guidance.”¹¹ First, SCP items “must meet specific nutritional benchmarks.”¹² Under this requirement, food items may not surpass the maximum recommended amount of certain “nutrients to limit” which include “total fat, saturated fat, trans fat, cholesterol, added sugars and sodium.”¹³ For example, a product may not contain more than

twelve grams of sugar per serving.¹⁴ Second, SCP items must “provide positive attributes” that individuals are encouraged to consume; these include “nutrients to encourage,” if healthy vitamins or minerals are contained in the item, or “food groups to encourage,” if a desirable food group can be found in the item.¹⁵ Examples of “nutrients to encourage” are Vitamin A and calcium; examples of “food groups to encourage” are whole grains and vegetables.¹⁶



Fresh and frozen fruits and vegetables without any additives are automatically

deemed Smart Choices.¹⁷ However, nineteen other food categories are considered for Smart Choices labeling by the program, including “cheese and cheese substitutes; snack foods and sweets; fats, oils and spreads.”¹⁸ According to Marion Nestle, Nutrition Professor at New York University, “[t]he object of this is to make highly processed foods appear as healthful as unprocessed foods, which they are not.”¹⁹

Kraft Foods, Kellogg’s, PepsiCo, and General Mills are among the ten companies who have signed up for the SCP, paying up to \$100,000 per year to participate.²⁰ Over two thousand products have been deemed Smart Choices as of September 29, 2009; the expectation is that this total will soon double.²¹

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'Smart Choices,' Continued

Supporters of Smart Choices

Those who support Smart Choices believe that it will aid a fast-paced society in making better food choices "in a way that reflects how people really shop."²² Michael Hughes of the Smart Choices Board states that while it might be optimal to have salad for dinner, "that's not a choice everyone will make."²³ Therefore, "consumers' desires for taste" must be considered.²⁴ The easily-identifiable labeling potentially allows consumers to make efficient shopping selections that favor healthier food choices.



Critics of Smart Choices

The Food and Drug Administration (FDA) is one organization that is skeptical of the SCP's methodology.²⁵ On August 19, 2009, the FDA and Department of Agriculture sent SCP a letter, stating their intent "to monitor and evaluate" the SCP system due to various concerns.²⁶ For example, FDA consumer research found that FOP labels make people less likely to consult back or side labeling.²⁷ Therefore, "both the criteria and symbols used in [FOP] and self-labeling systems [must] help consumers make healthy food choices."²⁸ The letter stated that it would focus on evaluating whether SCP's criteria were "stringent enough to protect consumers against misleading claims."²⁹ The letter further stated that the groups would monitor to see if labels "were inconsistent with the Dietary Guidelines for Americans; or had the effect of encouraging consumers to choose highly processed foods and refined grains instead of fruits, vegetables and whole grains."³⁰

Others also question the misleading and possibly fraudulent nature of the program.³¹ Michael Jacobson, Executive Director of the Center for Science in the Public Interest, once served on the Smart Choices nutritional criteria panel.³² He quit after realizing that the panel was "dominated by members of the food industry, which skewed its decision."³³ Crucially, Jacobsen said that the criteria permit foods that contain added nutrients to bear the Smart Choices seal. This "could mask shortcomings in the food"—such as bread made with no whole grain but with added nutrients—that qualifies for the Smart Choices seal.³⁴ Jacobsen also questioned the practice of permitting Smart Choices labels on "both regular and light mayonnaise, which could lead consumers to think they are both equally healthy."³⁵

Some question the propensity towards self-regulation in general.³⁶ Commentators in the *New England Journal of Medicine* have said that "self-regulation . . . could go far toward improving the healthfulness of foods sold" but only if it does "not displace meaningful external regulation."³⁷ Furthermore, they insisted, "some forms of communication may impede rather than facilitate informed choices."³⁸

Negative press on the SCP has led to institutions wishing to disassociate their names from the program.³⁹ While members who sit on the Smart Choices Board come from the American Dietetic Association, the American Diabetes Association, and Tufts University's School of Nutrition, each of these institutions has asked that Smart Choices remove their institution's names from its website, so as not to be affiliated with SCP.⁴⁰

Alternative Regulation: The FDA

The Food, Drug, and Cosmetic Act (FDCA) of 1938 broadly delegated the authority of the Secretary of Health and Human Services to regulate food labels to the FDA. The FDCA permits the FDA to regulate "any vitamin, mineral, or other nutrient required to be placed on the label

and labeling of food under this Act . . . if the [FDA] determines that such information will assist consumers in maintaining healthy dietary practices."⁴¹ Furthermore, the FDA "may by regulation require any information required to be placed on the label or labeling . . . to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the [FDA] determines that such highlighting will assist consumers in maintaining healthy dietary practices."⁴² The FDCA also demands that labels not be "misleading." To decide if labels are misleading, "there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal [material] facts."⁴³ A violation of the FDCA thus gives the FDA extensive power to correct such mislabeling.

"THEREIN LIES ONE PROBLEM WITH [THE SMART CHOICES PROGRAM]: A LABEL PROVIDING ONLY CALORIC CONTENT, SERVING SIZE, AND WHETHER A FOOD IS A GOOD SOURCE OF SOMETHING DOES NOT PROVIDE A FULL SPECTRUM OF NUTRITIONAL INFORMATION TO THE CONSUMER."

Therein lies one problem with SCP: a label providing only caloric content, serving size, and whether a food is a good source of *something* does not provide a full spectrum of nutritional information to the consumer. The SCP labels products with added minerals as Smart Choices. Accordingly, the public may choose a food otherwise devoid of nutrients and packed with empty calories—its only benefit being added minerals—and may detrimentally rely on the assumption that it has health benefits based on the SCP label. To prevent this, a food label should be forced to disclose that while minerals are added to the product, so are negative items like refined sugars. It should also

(Smart Choices,' Continued on page 9)

‘Smart Choices,’ Continued

disclose that there are sources by which one can find minerals from naturally occurring products, such as fruits, vegetables, or whole grains, that lack those added sugars (or other negative added items). Obviously, this much information on a FOP labeling scheme seems impractical. But not only is it unfair to include only the positive aspects of a product without the whole picture of a product, it also violates the FDCA.

“[S]ERVING SIZE SHOULD BE POSTED ALONGSIDE THE NUMBER OF SERVINGS SO THAT ONE BOWL OF CEREAL DOES NOT INADVERTENTLY TURN INTO THREE BOWLS, EFFECTIVELY TRIPLING THE ALLOWABLE SUGAR CONTENT OF A ‘SMART CHOICE.’”

In addition, the FDCA requires “[p]rominence of information on [a] label.”⁴⁴ The Act states that “if any word, statement, or other information required by or under authority of this Act [that] appear[s] on the label or labeling is

not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use” the item will be deemed misbranded.⁴⁵ The FDCA further mandates that the “serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food” be provided on a food label.⁴⁶ While the number of servings in a container is prominently posted on SCP products, the size of the serving is not. The average consumer, however, may bypass this pertinent information on the back of a product when they see only FOP labeling on a SCP product. Accordingly, serving size should be posted alongside the number of servings so that one bowl of cereal does not inadvertently turn into three bowls, effectively tripling the allowable sugar content of a “Smart Choice.”

A new FDA-regulated food system for front-of-package labeling may be the best solution to ensure that uniform, accurate, and equitable nutritional information

is provided to the public. Since the FDA does not have a profit-based relationship with food companies, it may be a more equitable rule maker for nutritional standards than is the SCP program. Since companies must pay to be a part of the SCP, an FDA-regulated system may also ensure access to smaller food companies that perhaps could not afford SCP’s benefits. Such FDA involvement may be close in the future; Michael R. Taylor, a Senior FDA adviser, has said that the FDA “would consider the possibility of creating a standardized nutrition label for the front of packages.”⁴⁷ The ideal labeling system would address the foregoing concerns and guide Americans to making truly “smarter” choices. ☼



‘Pregnant with Power,’ Continued

Because of the abnormal delays and inconsistent protocol used in the Plan B switch, the district court, under the power granted by the Administrative Procedure Act (APA),²⁸ overruled FDA’s refusal to provide non-prescription access to Plan B to seventeen-year-old women.²⁹ According to § 706(2)(A) of the APA, the court may so act when it concludes that an agency’s findings are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.”³⁰ Throughout his decision, Judge Korman was unwavering in his opinion that the delay in FDA’s decisions as to the supplemental new drug applications submitted by the Plan B manufacturer were a direct result of political interference, instead of being rooted in scientific evidence.³¹ In addition to

“[T]HE DELAY IN FDA’S DECISIONS AS TO THE SUPPLEMENTAL NEW DRUG APPLICATIONS SUBMITTED BY THE PLAN B MANUFACTURER WERE A DIRECT RESULT OF POLITICAL INTERFERENCE, INSTEAD OF BEING ROOTED IN SCIENTIFIC EVIDENCE.”

FDA’s deviation from its routine protocol, the court also noted that Plan B is available in most other industrialized nations without a prescription or age restriction—that is, without a BTC restriction.³² Because FDA acted inconsistently with the scientific evidence of Plan B’s safety, and because other scientifically advanced countries find no problem with unre-

stricted sale of Plan B, the court surmised that FDA’s determination that it needed to restrict the sale of Plan B was arbitrary.³³ In order to strike a balance between FDA’s concern and the citizens who demand no point-of-sale restrictions for the drug, the court ordered that Plan B should be made available behind-the-counter to women age seventeen and older.³⁴

Opposing Views of These Roles

While Judge Korman and others view political interference in the OTC switch of Plan B as disgraceful, certain religious groups and opponents of more liberal access to the drug find Judge Korman’s

(‘Pregnant with Power,’ Continued on page 10)

‘Pregnant with Power,’ Continued

decision to permit Plan B behind-the-counter sale to seventeen-year-old women to be similarly politically driven.³⁵ For example, Moira Gaul of the Family Research Council finds that Judge Korman may have allowed his own personal views to affect his decision.³⁶ Gaul suggests that allowing the courts to decide health-based issues diminishes FDA’s role to manage drug regulations.³⁷ The Family Research Council is also concerned that easier access to the drug could increase promiscuous behavior among teens.³⁸



In considering Judge Korman’s entire opinion, it seems that Gaul fails to take into account the court’s deference to FDA. While it is true that Judge Korman ordered the BTC sale of Plan B to women seventeen and over without remanding that decision back to FDA, there is no indication that this decision lacked scientific support. The court did not exercise extraordinary power or

make the drug available to all age groups without a prescription; that decision was in fact remanded to FDA.³⁹ Thus, Gaul’s assertion that the court’s decision was grounded in politics seems to ignore the scientific facts that support its decision.

Yet Gaul is not alone in her criticism of Judge Korman’s decision. Almost three months after Judge Korman ordered FDA to make Plan B available to seventeen-year-olds without a prescription, Concerned Women for American, Christian Pharmacists Fellowship International, and Christian Medical & Dental Associations filed for leave to intervene in the matter.⁴⁰ The groups were outraged by FDA’s decision not to appeal the March decision and sought to assert their interest in assessing the safety and efficacy of the drug.⁴¹ The interveners also argued that the decision circumvented the rulemaking process, which would have generated the information that they desired regarding the drug.⁴² Judge Korman, however, denied the motion for leave to intervene after the groups failed to establish standing within the proper timeframe.⁴³ Furthermore, Judge Korman found their argument regarding FDA’s rule-making process unpersuasive because it erroneously stated FDA’s actual policy, which holds that rulemaking is unnecessary when the process is initiated by a Citizen Petition (as was the case here).⁴⁴

Conclusion

FDA is best equipped to evaluate the scientific evidence objectively in order to fulfill its mission to protect and promote the public health, but FDA must strike a better balance between discerning what is medically necessary and considering certain public demands. If the FDA fails to do so, the court should exercise the power of review under the APA to achieve the best possible public health outcome. Whether activist groups agree with this specific decision regarding Plan B, it is reassuring to see that the system of checks and balances reaches all areas of our federal system. Ultimately the court put the scientific evidence first, and kept the public, rather than politics, in mind in its decision. ☼

“FDA IS BEST EQUIPPED TO EVALUATE THE SCIENTIFIC EVIDENCE OBJECTIVELY IN ORDER TO FULFILL ITS MISSION TO PROTECT AND PROMOTE THE PUBLIC HEALTH, BUT FDA MUST STRIKE A BETTER BALANCE BETWEEN DISCERNING WHAT IS MEDICALLY NECESSARY AND CONSIDERING CERTAIN PUBLIC DEMANDS.”

‘Reverse Payments,’ Continued

sumers, drug prices remain elevated until the generic is launched. These settlement agreements help to allocate the risk for both parties—the risk to the generic company of losing millions in patent infringement damages and the risk to the brand company of losing millions in higher priced drug sales made possible by the lack of price competition.

Early Cases Protected Patent Rights Despite Anti-competitive Effect of Reverse Payments.

The fact that patent holders were paying potential infringers raised an immediate red flag under antitrust law. Patents by their nature create monopolies, which antitrust law was created to eliminate.⁸ In 2003, the Sixth Circuit held that a reverse payment settlement agreement was a “horizontal agreement to eliminate competition in the market” and a “classic example of a per se illegal restraint on trade” in violation of § 1 of the Sherman Act.⁹ In the years that followed, however, the Second,¹⁰ Eleventh,¹¹ and Federal¹² Circuits held that reverse payments are not an

antitrust violation. In each of these cases, the settlement of a patent infringement lawsuit involved the brand company paying the generic company millions of dollars in exchange for a delay in market entry of the generic drug.¹³

These courts reasoned that as long as the settlement agreement neither extends beyond the scope of the patent in term or coverage, nor manipulates the generic company’s 180-day exclusivity such that it further delays other generic companies

(‘Reverse Payments,’ Continued on page 11)

'Reverse Payments,' Continued

from launching drugs, reverse payments will be upheld as lawful.¹⁴ Courts determine antitrust violations of the Sherman Act by using the "rule of reason" analysis.¹⁵ This involves a three step approach to determine (1) the relevant market, (2) whether the brand company has market power within the relevant market, and (3) whether the reverse payments have an adverse effect on competition in that market.¹⁶ If all anticompetitive effects of the settlement agreement are within the exclusionary power of the patent, meaning the delay of market entry is within the patent term and scope, some courts have declined to find an antitrust violation.¹⁷ Because patent law provides an assumption of patent validity and because public policy strongly encourages litigation settlements, courts generally allow reverse payments as long as the terms of the settlement did not extend the anti-competitive effects beyond that "exclusionary zone" of the patent.¹⁸

Although it may appear that circuits are split on the issue of reverse payments, it is yet to be determined whether the Sixth Circuit will hold all reverse payments per se illegal. In the Sixth Circuit case, the agreement involved a payment by the brand company to the generic company for delay of a non-infringing drug product which would compete with the brand name drug.¹⁹ This agreement involved the delay of marketing a formulation of the drug that was not patent protected but would compete with the brand drug.²⁰ Such an agreement would be an antitrust violation even under the reasoning of the Second, Eleventh, and Federal Circuits. But the question remains as to whether the Sixth Circuit will consider an agreement that is within the "exclusionary zone" of a patent to be a per se violation of the Sherman Act.

The New Administration May Bring Changes to Reverse Payments

There has been recent legislation in response to reverse payment settlement agreements. The Medicare Prescription Drug, Improvement, and Modernization



Act (MMA) mandates that the Federal Trade Commission (FTC) receive a copy of any settlement agreement between a brand and generic company in a patent infringement litigation.²¹ The MMA also has safeguards against those settlement agreements that try to manipulate and postpone the 180-day exclusivity period for the first generic to file a paragraph IV certification.²² Recently, a bill has been introduced into the Senate (S. 369) which would amend the Clayton Act so that it will be unlawful for anyone involved in a patent infringement case to (1) settle for anything of value *and* (2) delay use or manufacture of the drug for a period of time.²³ This would virtually eliminate the ability of brand and generic companies to use reverse payments in patent litigation settlement agreements.

In the past, the Department of Justice (DOJ), upon invitation, has opposed certiorari in support of reverse payments.²⁴ Recently, however, the DOJ has aligned itself with FTC stating that reverse payments should be presumptively unlawful because they "inappropriately permit a patent holder to escape the risk of patent invalidation and distort the statutory process that leads to competition in the face of

patent claims."²⁵ If the reverse payment is in excess of litigation costs, and the settlement agreement shortens the period of patent exclusivity, the defendant can rebut the presumption of unlawfulness by showing that the agreed upon entry date of the generic drug is that which would have been expected had the patent infringement litigation gone to judgment.²⁶ This requires an evaluation of the likelihood that a judgment in the patent litigation would have resulted in patent invalidity prior to patent expiration.²⁷

The DOJ's model is vague and unworkable and would likely result in various interpretations among the circuits. It would be difficult, if not impossible, to determine whether the underlying patent would have been invalidated without a full patent infringement trial on the merits. The current analysis by the Second, Eleventh, and Federal Circuits allows for a clearer set of rules for brand and generic companies to follow when determining settlement agreements. These rules also provide a fair balance of avoiding unreasonable restraints on trade under antitrust law while allowing patent monopolies. To date, the Supreme Court has denied certiorari for all appealed reverse payment cases. With a rising trend in opposition against reverse payments, however, we may see the Supreme Court tackling this issue in the near future. ☼

"THE DOJ'S MODEL IS VAGUE AND UNWORKABLE AND WOULD LIKELY RESULT IN VARIOUS INTERPRETATIONS AMONG THE CIRCUITS. IT WOULD BE DIFFICULT, IF NOT IMPOSSIBLE, TO DETERMINE WHETHER THE UNDERLYING PATENT WOULD HAVE BEEN INVALIDATED WITHOUT A FULL PATENT INFRINGEMENT TRIAL ON THE MERITS."

‘Managing PBMs,’ Continued

pharmacy services that compete with retail pharmacies by dispensing certain covered prescriptions directly through the mail to patients, resulting in cost savings to patients and benefit providers.¹⁷ PBMs also provide services to monitor and manage benefits claims, as well as programs to educate on disease management, compliance strategies, and other patient issues, to encourage cost-effectiveness.¹⁸

Criticism of PBMs

Perhaps the biggest criticism facing the current PBM structure is the lack of transparency surrounding the rebates negotiated among the parties.¹⁹ In essence, the public wants to know how big of a “cut” the PBMs are getting. Some argue that, armed with this information, benefit providers and patients will wield more bargaining power to negotiate lower drug prices.²⁰ In response to this lack of transparency and regulation, PBMs have faced state law claims of unfair and deceptive practices brought by private parties and claims of unfair trade practices brought by the Department of Justice (DOJ) and many states.²¹ For example, parties acting as “private attorneys general” have claimed that “PBMs are failing to disclose and pass on” savings to benefit providers and “are contributing to the escalation in prices of prescription drugs by keeping the lion’s share of rebates,” which they believe “is in the billions of dollars annually.”²² A similar suit against Medco, brought by the DOJ and twenty state attorneys general, was settled for \$29 million.²³ In total, between 2004 and 2008, the three largest PBMs have been subject to over \$370 million in litigation damages over claims of “fraud; misrepresentation to plan sponsors, patients, and providers; unjust enrichment through secret kick-back schemes; and failure to meet ethical and safety standards.”²⁴ Several states have also passed legislation regulating PBM practices, and others have considered such regulation,²⁵ with input from Federal Trade Commission (FTC).²⁶ These actions all indicate that, in addition

to being subject to criticisms of the lack of transparency generally, PBMs also suffer due to the negative inferences that others draw from this lack of disclosure.

The Benefits of PBMs

Despite these criticisms, PBMs have been successful in reducing the costs of drug benefits for their participating benefit providers, and many have found the competition among PBMs sufficient to compensate for the lack of transparency in the marketplace. For example, a U.S. General Accounting Office (GAO) study found that “[t]he average price PBMs negotiated for drugs from retail pharmacies was about 18 percent below the average cash price customers would pay at retail pharmacies for 14 selected brand-name drugs and 47 percent below the average cash price for 4 selected generic drugs.”²⁷ Thus, the negotiating power and positioning of the PBMs in the supply chain allowed them to generate substantial savings for patients enrolled in benefits plans as compared to cash-paying patients.

“[T]HE NEGOTIATING POWER AND POSITIONING OF THE PBMs IN THE SUPPLY CHAIN ALLOWED THEM TO GENERATE SUBSTANTIAL SAVINGS FOR PATIENTS ENROLLED IN BENEFITS PLANS AS COMPARED TO CASH-PAYING PATIENTS.”

Considering this and similar evidence, government agencies previously have not found the degree of disclosure to be inadequate because of the ample degree of competition among PBMs. An FTC and DOJ investigation of healthcare competition concluded that “[j]ust as competitive forces encourage PBMs to offer their best price and service combination to health plan sponsors to gain access to subscribers, competition also encourages disclosure of the information health plan sponsors require to decide on the PBM with which to contract.”²⁸ Likewise, in a study of PBMs that operate their own mail-order pharmacy services, the FTC deter-

mined that its “data suggest that competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests.”²⁹ In this vein, commentators have suggested that “rebate transparency can be handled through private contracts, because there is no barrier to a plan sponsor negotiating an arrangement providing it with access to the PBMs’ rebate information.”³⁰ Despite these defenses of the PBM industry, the calls for reform have continued, including in the current debate of broad-based healthcare reform.

Current PBM Reform Efforts

Recently, legislators and consumer groups have pushed for PBM transparency measures as part of the 2009 healthcare reform efforts partially embodied in the Senate’s proposed America’s Healthy Future Act (AHFA).³¹ The current proposal originated in an amendment sought by Senator Maria Cantwell (D-Wash.),³² which was approved by the Senate Finance Committee³³ and incorporated into the Senate bill.³⁴ Under the current Senate proposal, a PBM will be required to confidentially disclose information on:

- (1) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed
- (2) The aggregate amount, and the type of rebates, discounts, or price concessions . . . that the PBM negotiates that are attributable to patient utilization under the plan, and . . . that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.
- (3) The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail phar-

(‘Managing PBMs,’ Continued on page 13)

'Managing PBMs,' Continued

macies, and mail order pharmacies, and the total number of prescriptions that were dispensed.³⁵

The House of Representatives' bill, the Affordable Health Care for America Act, incorporates similar PBM transparency provisions³⁶ and was passed by the House on November 7, 2009.³⁷ Both measures would only require transparency and rebate disclosure, not that rebates be passed through; however a failure to disclose would be enforced by the same penalties that apply under the Medicare rebate statute,³⁸ which may include \$10,000 for each day that information is not provided or \$100,000 for each item reported falsely.³⁹

Upon its proposal, the Cantwell amendment was supported by over thirty consumer, labor, and Medicare beneficiary groups.⁴⁰ These groups wrote letters urging Senate leaders to include the amendment in any final package that reaches the Senate,⁴¹ using such language as "[n]o other segment of the health care market has a record of such deceptive, egregious and anti-consumer practices."⁴² This lobbying effort is further supported by the GAO's determination that the amendment would be budget-neutral, i.e., that the disclosure provisions would not increase PBM costs that would be passed on to benefit providers.⁴³ These reform efforts reflect the lobbyists' position that the previous reliance on competition and contract bargaining to generate appropriate levels of transparency has been insufficient.

The Business of Healthcare Reform

Because of this relationship between competition and transparency, consolidation in the PBM industry will influence efforts at reform. In 2007, over half of all prescriptions filled by PBMs were filled by Medco, CVS/Caremark, or Express Scripts.⁴⁴ The consolidation continued in 2009, with Express Scripts purchasing the PBM division of Wellpoint (the fourth largest PBM by market share in 2007)⁴⁵

and Medco reportedly leading the bidding on the PBM division of Aetna (the tenth largest).⁴⁶ The increased market clout and bargaining power of PBMs in a rapidly consolidating industry will thus influence the ultimate benefits of any transparency measures.

In addition, apart from transparency measures incorporated into any healthcare reform legislation that is passed, the PBMs will directly benefit from the expected increase in access to medical insurance. Robert Hodgson, the manager of the BlackRock Healthcare Fund, expects PBMs in particular among healthcare sectors to benefit from the AHFA: "Someone is going to have to be responsible for managing the drug [expenditures], helping people get the best prices, helping [do] things by mail, helping—whether it's the HMOs or whether it's a government-run plan—put those packages and those programs together."⁴⁷ In other words, PBMs will play the same role in the pharmaceutical supply chain post-reform, but with an expanded, and potentially more profitable, scope.

Creating a Win-Win for Big Business and Small Patient

With increased consolidation and expanded access to their services, PBMs stand to profit significantly in the near future. For instance, fewer PBMs should give the survivors increased bargaining power to negotiate better rebates from pharmaceutical manufacturers.⁴⁸ The increased market size will also expand the role of PBM services in containing costs and managing formularies, reinforcing their additional bargaining power. It should also increase demand for effective ancillary services like mail-order pharmacies, claims adjudication, and quality-



focused programs, for which PBMs earn additional administrative fees. Even if the additional transparency requirements result in lower margins, this would be offset by higher volume. Accordingly, given the scope of the expected market expansion, it is likely that PBMs will ultimately benefit from healthcare reform.

Nonetheless, it is clearly patients and benefit providers who are intended to benefit from the Cantwell amendment's transparency measures. Transparency should be the price exacted—the trade-off—for the PBMs' increased role in the marketplace. As advocates have argued, "A market needs three things to function competitively and effectively: choice, transparency, and lack of a conflict of interest."⁴⁹ If, as many expect, disclosure result in lower prices, this will be an immediate benefit for these groups to the extent that disclosure increases the size of the rebate that is passed on to them without increasing the prices paid by the PBMs. "If PBMs reduce drug prices, it's possible—depending on their health plan and the company they work for—that some patients might pay less for drugs."⁵⁰ Yet despite the GAO's determination that the measure is "budget neutral,"⁵¹ the Pharmaceutical Care Management Association lobbying group and some PBM executives believe the amendment will actually increase prescription drug costs, because it would

(Managing PBMs,' Continued on page 14)

‘Managing PBMs,’ Continued

give manufacturers and pharmacies more leverage in the negotiation of pricing, reducing the margins realized by the PBMs.⁵²

Whatever the immediate impact of the Cantwell or similar amendments on drug prices may be, patients and benefit providers still stand to benefit from the effect of healthcare reform on the PBM industry. For example, transparency should also promote savings by reducing the need to “litigate challenges to egregious, deceptive and anticompetitive PBM conduct.”⁵³ Benefit providers have also followed the lead of Congress by taking immediate action and lobbying PBMs themselves, with nearly sixty large employers banding together to demand greater transparency from PBMs⁵⁴ via the previously favored private contracting method.⁵⁵ Finally, even in the event that drug prices increase incrementally, a large number of patients—formerly cash payors and now members of PBM-managed

plans under the AHFA reforms—will still see their drug prices fall by as much as fifty percent.⁵⁶

None of these secondary benefits should overshadow the ultimate goal and likely consequence of the transparency measures: to pass more of the rebate savings along to drug purchasers. Ultimately, this transparency measure, when incorporated into the broader healthcare reform initiative, would benefit both big business and small patient. Pharmacy benefit managers are good at what they do—negotiating the middle of the pharmaceutical supply chain to bring savings to benefit providers and patients. Congress should leverage this expertise and ensure that healthcare reform provides access to PBMs and increased rebate savings for all patients. In exchange, enlarging the role of PBMs in the healthcare marketplace will provide significant new profit-making opportunities for the industry, which investors are already recognizing. Undoubt-

edly, the result of this reform would be a mutually beneficial relationship, and the foundation of this mutually beneficial relationship will be transparency. ☼



‘To Tell or Not to Tell,’ Continued

Full disclosure of an error includes a description of the error, an acknowledgment of responsibility, and an apology.³⁴ But a careful choice of words may be used to subvert this disclosure by not informing the patient of the actual error that occurred and the full extent of the effect on his or her health.³⁵ Another study estimated that nationwide, physicians are only disclosing errors to patients about one-third of the time.³⁶ These studies demonstrate the great disconnect between the ideals that support error disclosure and its actual performance.

Reasons for Non-disclosure of Errors

The psychological underpinnings that cause physicians to resist disclosing medical errors to patients are complex and can be traced to the basic structure

of medical training:

Admission of errors is difficult for physicians. Historically physicians in residency training have trained in a culture where disclosure to peers is considered a sign of weakness. Instead skill in “roundsmanship” is valued, that

is, creative and contemporaneous responses to cover deficiencies or errors when reporting to more senior physicians.³⁷

“CONSEQUENTLY, THIS ‘[MEDICAL] NARCISSISM’ CREATES A SIGNIFICANT PSYCHOLOGICAL BARRIER IN ALLOWING PHYSICIANS TO ACKNOWLEDGE THAT THEY COULD HAVE COMMITTED AN ERROR, WHICH IN TURN LEADS TO THE ‘PHENOMENON OF MEDICAL ERROR CONCEALMENT’ AND OTHER EFFORTS TO OBSCURE THE OCCURRENCE AND FACTS RELATED TO THE ERROR.”

“Medical narcissism” is defined as the need of health professionals to preserve their self esteem leading to the compromise of error disclosure to patients.³⁸ Additionally, there is “an atmosphere in health care that can breed narcissistic inclinations and attitudes that make it very difficult to disclose medical errors truthfully and ethically.”³⁹ Consequently, this “narcissism” creates a significant psychological barrier in allowing physicians to acknowledge that they could have committed an error, which in turn leads to the “phenomenon of medical error concealment” and other efforts to obscure the occurrence and facts related to the error.⁴⁰ The “rationalizing” of errors by medical professionals is another mechanism

(‘To Tell or Not to Tell,’ Continued on page 15)

'To Tell or Not to Tell,' Continued

Mister Boffo - By Joe Martin



"Yes, we disclose. . . ."

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whereby the significance of the error is minimized by terming it as an "incident," by stating that it did not conclusively result in harm to the patient, and, if harm did occur, that it was minimal and not "anybody's fault."⁴¹

The primary factor that is widely understood to limit full error disclosure is a fear of resultant medical malpractice lawsuits.⁴² A landmark study suggested, however, that non-disclosure of errors is more likely to lead patients to change physicians and seek legal advice regarding the errors.⁴³ In contrast to patients reporting that error disclosure would be unlikely to lead them to sue for medical malpractice are the results of recent financial risk analyses using mathematical modeling to evaluate the financial risks associated with error disclosure. While conceding that disclosure of medical errors is "the ethically right thing to do," the authors of the study concluded that disclosing errors would likely prompt patients to sue, resulting in increases in medical malpractice costs.⁴⁴ Nonetheless, it is questionable whether a desire to avoid financial responsibility for mistakes is a valid basis for abandoning an ethical obligation.

Other significant factors contributing to non-disclosure include concerns about loss of reputation and referrals, the desire of physicians to remain self-regulated, and the fear of retribution for

reporting.⁴⁵ While there are many reasons for non-disclosure of errors, none of these negate the basic ethical imperative for disclosure.

Possible Effects of the PSA

In 1999, an Institute of Medicine publication reported that as many as ninety-eight thousand Americans die in hospitals each year as a result of medical error.⁴⁶ Viewed in the context of the significant biases that afflict voluntary reporting of adverse events, these statistics may have represented an under-reporting.⁴⁷ Since the publication of this report, issues of patient safety and medical error reporting have received a great deal of attention from the medical community.

The effects of legal mandates on medical error disclosure and eventually patient safety are yet to be fully understood. In theory, the PSA should result in an increase in the number of error disclosures to patients and to DHHS. There may be no effective way, however, of validating that this is indeed occurring. Certain occurrences fall within well-defined classifications of "serious preventable adverse events," such as burns sustained by a patient while undergoing surgery or errors in blood transfusions.⁴⁸ Other "incidents," such as the one described above where a patient dies following attempts to suction blood from around the heart, may be "rationalized" as "no one's

fault."⁴⁹ Truly egregious errors are likely to go unreported due to concerns of liability and fears of negative publicity following reporting to DHSS. Hence, in the absence of independent monitoring, the mandated disclosure of errors will not necessarily ensure the compliance of healthcare providers and hospitals.

Conclusions

The creation of a law requiring disclosure of medical errors in New Jersey indicates that the legislature does not consider valid any reasons put forward for non-disclosure. Data collected through the mandatory reporting system can identify the factors that lead to medical errors and in turn eliminate or minimize these factors as far as feasible. Additionally, patients are provided information to make informed choices about future medical care. The effect that this law will have on the frequency of medical malpractice suits remains debatable.⁵⁰ Enactment of the PSA is a significant step toward mandating transparency in healthcare. Whether a law can truly bring about the desired transparency and result in improved patient safety remains to be seen. ☼

"WHILE THERE ARE MANY REASONS FOR NON-DISCLOSURE OF ERRORS, NONE OF THESE NEGATE THE BASIC ETHICAL IMPERATIVE FOR DISCLOSURE."

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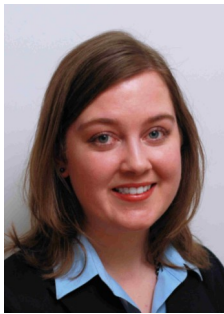
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Student Contributors



Sarah Geers will graduate in May with a concentration in intellectual property and a continuing interest in health law. Prior to law school, she worked as a pharmaceutical scientist at Merck & Co., Inc., where she developed drug formulations for clinical trials and marketed products. She interned in the Merck Patent Department first while working as a research scientist and later while at Seton Hall. Last summer, she was a summer associate at Cravath, Swaine & Moore LLP in New York, where she will return in 2011.



Diana Giampiccolo is a first-year student with an interest in health law. She graduated from Seton Hall University in May 2009 with a B.A. in English and a minor in Russian and East European Studies. From 2006 to 2009, she worked as a personal injury and real estate paralegal at Spector Foerst & Associates in Millburn, New Jersey.



Nicole Hamberger, a 2L, graduated from Gettysburg College in 2008 with an English major and a Writing minor. In the summer of 2009, she completed a legal externship at St. Michael's Medical Center in Newark, New Jersey. In college, she assisted in medical malpractice and personal injury cases as an intern for two summers at Gold Albanese & Barletti in Morristown, New Jersey, and for one summer at Wolf Block Brach Eichler in Roseland, New Jersey.



Nicole Ho is a third-year student interested in health law and intellectual property law. Prior to law school, Nicole worked as a research associate at Bristol-Myers Squibb and Merck Research Labs. She specialized in early drug discovery, specifically oncology research. While at Seton Hall, Nicole interned at Merck's patent department and at the intellectual property law firm Lerner, David, Littenberg, Krumholz & Mentlik. Nicole will continue as an associate at LDLKM when she graduates from Seton Hall Law in May.



Dr. Neelu Pal is a first-year law student and a board-certified general surgeon who completed residency training in 2005 at University of Medicine and Dentistry in Newark. She went on to complete fellowship training in bariatric surgery at University Medical Center at Princeton in 2007. She is currently self-employed and in the process of starting a private practice in Jersey City. She believes that the law and medicine are based on similar profound ethical principles and is interested in this confluence and the impact that it has on healthcare delivery. She is especially interested in the areas of patient safety, fraud and abuse, and drug and device law.

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Health Law Forum News

The NY Health and Hospital Corporation

Newark, NJ—October 5, 2009

On October 5, 2009, the Health Law Forum hosted guest speaker Stacy-Ann Christian, J.D., M.P.H., who discussed her role as the Senior Director of the Office of Clinical and Health Services Research at the New York City Health and Hospitals Corporation (HHC). As part of the Health Law Forum's ongoing speaker series, Stacy-Ann Christian spoke at length about her current work and the many capacities it entails including lawyer, administrator, policy expert, and businesswoman.

Ms. Christian provided a brief overview about her educational and professional background. After law school, she first clerked for an Essex County judge and then entered private practice. Upon completion of her Master of Public Health degree, she went in-house at a pharmaceutical company. After obtaining extensive contracting experience, Ms. Christian joined HHC. At HHC, she is responsible for managing all legal and contractual aspects of pharmaceutical and medical device studies conducted at the thirteen hospital and healthcare facilities that are part of HHC. Ms. Christian described how such wide-ranging responsibility entails the ability to understand the human and business aspects of research contract negotiations; on one end are the research subjects, who are typically uninsured or underinsured and whom HHC is charged with serving, and on the other is the need to advance research and ensure that HHC is able to receive funding so that it can continue to provide its services.

Ms. Christian finally discussed her experience obtaining the M.P.H. degree, particularly noting that the team-based teaching method broadened her highly technical and analytical law-school thinking processes. At the same time, she explained that having her law degree helped her analyze public health problems in a more practical matter than some of her counterparts in the degree program. She further noted that the M.P.H. has been highly marketable, providing opportunities to pursue a career spanning both policy and law.

The Health Law Forum would like to thank Ms. Christian for taking the time to speak about her experiences and for providing advice and opportunities in the field. The Health Law Forum is proud to work in partnership with such a valuable health law resource. ☀



HLF Director of Online Development Jordan Cohen (left) and HLF Vice President Matt McKennan (right) welcome incoming health law students at new student orientation in August. Copies of the Health Law Outlook were distributed to new 1Ls, who frequently contribute to the HLO in their first semester.

Launch of the Health Law Forum Website

The Health Law Forum is excited to announce the launch of our website: www.healthlawforum.com. This site is entirely student-run and serves as a hub to both the Health Law Forum and the *Health Law Outlook*. At the site you can find all of the previous *Health Law Outlook* publications, as well as a calendar of the Health Law Forum's future events. We continuously update the site with information, including outlines for classes related to health law, links to other health law-related websites and blogs, and discussions and summaries of Health Law Forum events as they occur throughout the semester. Our hope is that the site will foster student collaboration and discussion, as well as networking opportunities in the field of health law. ☀



More HLF News

Student Health Law Conference

Newark, NJ—October 16, 2009

On Friday, October 16, 2009, Seton Hall Law hosted the Third Annual Student Health Law Conference. The conference was co-sponsored by Seton Hall Law and the American Society of Law, Medicine & Ethics (ASLME). Students from law schools across the country attended the day-long event to explore career opportunities in the field of health law. Associate Dean Kathleen Boozang kicked off the conference with an entertaining and far-reaching explanation about the scope of a health lawyer's responsibilities. Her introduction touched on the role of corporate counsel at non-profit hospitals, issues of fraud and abuse encountered by government attorneys, and the role of lawyers in international health policy debates involving healthcare provision under a totalitarian regime.

Soon after Dean Boozang's charge, students attended various panels throughout the Seton Hall Law campus. Each panel was composed of distinguished professionals in the health law field, including several Seton Hall alumni. Practitioners from various organizations and institutions including the U.S. Department of Health and Human Services, Gibbons P.C., Johnson & Johnson, and Blue Cross Blue Shield of New Jersey provided career advice and guidance. The panel sessions covered such topics as Pharmaceutical In-house Counsel, Health Information Technology, Starting Your Own Health Law Related Business, and Obtaining an L.L.M. in health law.

Each panel session included a brief overview by the panelists about their journey and experience in health law. Panelists also fielded questions from students. Common questions included topics such as how to get your "foot in the door", whether or not a scientific background is helpful in the pursuit of health law, and what areas of health law are emerging or bound for growth in the future. Panelists offered a broad range of suggestions and valuable insight. For instance, the panel of in-house counsel recommended, as a practical matter, working in a private firm or government position before making the transition in-house. The panel regarding government enforcement stressed internships at local levels and the potentially tremendous impact of federal regulation reform on future practice. Overall, the panel discussions illuminated the viability of a health law career even during a shaky economic climate due primarily to the growing breadth of health-related laws and regulations at both the state and federal level. The day ended with one final opportunity to meet fellow students, faculty, and panelists during a networking reception in the Seton Hall Law Atrium.



Conference attendees mingle at the networking reception in the law school atrium.

One of many panel discussions at the Student Health Law Conference.



Overall, the conference was an overwhelming success. As evidenced by the quality, number, and diversity of panelists and students in attendance, the program provided an excellent opportunity to explore the field of health law and to meet current and future colleagues across the spectrum of health law practice. ☼

Blood Drive

Newark, NJ—October 13, 2009

The fall semester blood drive was a tremendous success, thanks to volunteers from the Public Interest Network and the Health Law Forum. The drive was organized by HLF secretary Nicole Ho and was sponsored by the American Red Cross. Students donated in the Multipurpose Room of the law school and were treated to snacks and beverages. The fifty-one donations will help save 153 lives. Please join us when the Red Cross returns again next semester for the spring semester blood drive. ☼

Health Law Forum News

About the Health Law Forum

The Health Law Forum is a student organization at Seton Hall Law School for those interested in health law.

The Health Law Forum hosts speakers, panel discussions, community service projects, and networking events throughout each academic year.

The *Health Law Outlook* (HLO), a subsidiary of the Health Law Forum for students interested in health policy, hosts regular round-table discussions about current topics in the healthcare field. Each semester, HLO presents healthcare issues using debate, brain-storming, presentation, and Socratic method formats. Many of the articles included in newsletters are the product of these meetings and discussion.

This semester's HLO and HLF meetings and events included

- Speaker discussing the roles attorneys play in the coordination of research studies in hospitals and other healthcare organizations.
- Analysis of the current H1N1 pandemic, including its impact on a global, national, and regional level.
- Fall blood drive, co-sponsored by the Public Interest Network.
- Faculty discussion regarding student course selection for next semester.
- Launch of the new Health Law Forum website.



HLF 2009-2010 Executive Board:

Matthew Colford (3L), President

Matthew McKennan (2L), Vice President

Kaitlin Semler (3L), Treasurer

Nicole Ho (3L), Secretary

Jordan Cohen (2L), Dir. Online Devel.

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Stephanie Mazzaro (1L), SBA Rep.

Faculty Advisor:

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Visit our website at www.HealthLawForum.com

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Health Law Forum

Health Law Outlook

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